UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF VIRGINIA

ALEXANDRIA DIVISION

GILDA HAGAN-BROWN,	)	
Plaintiff,	)	
vs.	)	1:14-CV-01614-AJT-JFA
ELI LILLY AND COMPANY,	)	Hon. Anthony J.
an Indiana corporation,	)	Trenga
Defendant.	)	

The videotaped deposition of MATT KUNTZ, taken in the above-entitled cause, before Paula Ann Erickson, Certified Shorthand Reporter, Registered Professional Reporter and Notary Public, on May 6, 2015, at the Double Tree Hotel, 510 East Illinois Route 83, Mundelein, Illinois, at the approximate hour of 1:36 p.m.

Reported by: Paula A. Erickson, CSR, RPR, CLR

* * *

Effected Regulation?

A. Yes.

Q. And what is that?

A. It's a type of supplement, so it's changes being affected are -- is a mechanism by which the sponsor or the applicant can modify labeling without prior approval -- I'm sorry. You can update and implement a change to your labeling prior to receiving FDA's approval.

Q. And are you familiar with the circumstances in which that is permitted?

A. Yes, I am.

Q. What are those circumstances?

A. They include different types of manufacturing changes and also can include safety updates to labeling.

Q. Specifically are they permitted -- Strike that.

You said that there is other types of applications, however, that require prior approval; is that right?

A. Right.

Q. Are those frequently called -- What are those called within the regulatory jargon?

A. Prior Approval Supplement, PAS.

Q. Okay. And the Changes Being Effected Regulations are just those called CBEs?
A. CBEs.
Q. And Prior Approval Supplements, what do those relate to?
A. Those would relate to substantial modifications to labeling that aren't necessarily immediately a safety-related issue but sometimes they have some sort of safety component but often they can also be like new clinical data to support a dosing instructions or supplements for new populations to be added to labeling.
Q. And for Prior Approval Supplements, any proposed changes have to first be approved by the FDA before they are implemented?
A. That's correct.
Q. Whereas, in a CBE change, they can be implemented immediately; is that true?
A. Yes.
Q. They also are, of course, subject to FDA review, though, correct?
A. Yeah. They are still subject to FDA review and ultimately FDA approval.
Q. Okay. During the time that you worked

402

as a US Regulatory Associate for Cymbalta, did you ever have an occasion to see Lilly submit a CBE?

A. I don't recall to be honest. I just -- I don't know.

402

Q. Well, during your time as a US Regulatory Associate for Cymbalta, do you recall Lilly submitting any Prior Approval Supplements?

A. Yes. I remember -- and, you know, honestly, I wouldn't be surprised there would be CBEs. Those are just common lifecycle management activities. You know, as you have more data available, you would naturally want to the include it in your NDA.

402
Lack of foundation.

Q. That was actually going to be my next question. Are CBEs and Prior Supplemental Applications -- Prior Approval Supplements, are they common as part of the regulatory interfacing between Lilly and the FDA?

MR. TEEL: Object to the form. You can answer.

THE WITNESS: Yeah. I mean, they would be normal course of business and I would have expected both types of supplements to be submitted.

BY MR. WISNER:

Q. Okay. I just want to -- We are going to come back to Lilly in a second. I just want to know a little bit more about you. Do you have any medical training?

A. Yes. My background is in pharmacy.

Q. Can you please explain to the jury what your educational background is?

A. Yeah. Sure. So I have a bachelor's degree in pharmacy and then I also have what's called a Pharm.D. in pharmacy which is -- required a couple more years of pharmacy and then I have also an MBA.

Q. And you say you have a bachelor's in pharmacy. Can you explain to the jury what that means? What is the area of study of pharmacy?

A. So just pharmacy practice in general is what your degree is in. I didn't specialize or get any further certifications, so the bachelor's degree in pharmacy is a five-year program that is a general pharmacy curriculum.

Q. Is the purpose once you have completed the degree, you can open up a pharmacy? Is that the idea?

A. Sure. You could open a pharmacy, you

* * *

Q. That's okay.
A. I don't really remember anything else about it other than that. I think we were -- we were requested to go back and look for any submissions to FDA or any sort of correspondence with FDA around Discontinuation Adverse Events.
Q. So it had to have been before August 2012; is that fair?
A. Yes. It was.
Q. Okay. Do you recall if it was a class action or a personal injury case?
A. I'm sorry, I don't.
Q. Do you even know what those differences are?
A. I do. Sort of in the broadest sense at least.
Q. Okay. Okay. Do you recall working on -- And just do you mind if I use the word withdrawal or do you have a preference one way or the other?
A. I mean, I use the term Discontinuation Adverse Events, but I don't have a preference what you use.
Q. I might use withdrawal. I might use discontinuation symptoms. I will try to use

403
Lack of foundation.

discontinuation symptoms but I might mess up so I apologize if I do.

A. That's fine. Okay.

Q. When -- Do you recall doing any regulatory activities related to discontinuation symptoms?

A. With FDA, no, I don't.

Q. Do you recall doing any discontinuation-related issues with any regulatory body?

A. I don't recall.

Q. Now, you said you were a US Regulatory Associate. Did you also work on regulatory issues in other countries?

A. Not directly, although, we would be aware of any sort of ongoing interactions with at least the major regulatory authorities outside the US and, again, in the interest of patient safety, Lilly would often try to harmonize labeling, to the extent it was possible, given the different regional preferences and jurisdictions.

Q. The -- You have mentioned the word harmonize a couple of times. Can you explain to the jury what that means?

A. Yeah. So the -- Regulatory authorities in each country have their own set of requirements, regulations, and often pharmaceutical companies are trying to develop products to be marketed in worldwide, right, and so it becomes difficult when you have to develop a product under a certain set of rules in the US and a different set of rules in Europe and a different set of rules even for Japan and so harmonization is about trying for these three major regulatory regions to attempt to at least standardize, to the extent possible, their requirements.

Q. You said these three major ones. Are those the three primary regulatory groupings of -- of -- are those the three primary regulatory groupings?

A. Yes.

Q. And, I mean, there is obviously more than three countries in the world.

A. Right.

Q. What is your understanding of why there is those three primary regulatory groupings?

A. Well, those are the -- this is my understanding -- is that these are the three

* * *

meaningful.
BY MR. WISNER:
Q. You said fair and balanced. That's actually a term of art within Lilly, right?
A. A term of art? I believe, yes.
Q. It's actually a goal set by Lilly in its product labeling?
A. I think it's a goal established. I'm not sure if it's in regulation or not but yeah. It's a common vernacular in regulatory.
Q. And can you explain to the jury what fair and balanced means?
A. Well, it would just mean that the data are conveyed in a manner that is accurate, not misleading, not overstating or minimizing the data. You know, it's just it's a fair and balanced representation of the data.
Q. During your time at Eli Lilly, did you ever have an occasion where you thought that Lilly was not being forthright or honest in its disclosures in its US product labeling.
A. No.
Q. Previously I mentioned the word withdrawal and discontinuation symptoms. What is your understanding of that?

MR. TEEL: Object to the form.

MR. WISNER: Let me ask that a different way. Strike that.

BY MR. WISNER:

402
403

Q. What is -- What is discontinuation symptoms, to the best of your knowledge?

A. For Cymbalta specifically?

Q. Precisely. Yes.

A. That if you abruptly -- well, I don't even know if it's always abruptly; but if you stopped Cymbalta, you may experience certain adverse events around the time you discontinue and I believe things like nausea, jitteriness but I don't remember all the others. There is a list of them I know.

402
403
MIL

Q. Sure. And what is your understanding of how frequently that withdrawal risk occurs?

A. How frequently?

Q. Uh-huh.

A. Well, I do know that in the preparation for today, I was made aware that in the European label, it I think cites something like 45 percent or something of that nature.

Q. But prior to your preparation, you weren't aware of that fact?

A. I didn't recall it, no.

402 403 Q. Okay. While you were a US Regulatory Associate, was the issue -- the safety issue of discontinuation symptoms something that you considered to be important?

A. I don't remember ever having any sort of concern or issue with the way that the discontinuation events were labeled in the US.

Q. And during your time -- And did you ever hear any discussions amongst anybody at Eli Lilly that the labeling was somehow deficient or -- Strike that.

402 403 During your time at Eli Lilly, did you ever hear anyone discussing or mention to you that the Cymbalta label with regards to discontinuation symptoms was deficient?

402 403 A. I don't recall ever hearing that.

Q. Do you ever recall having any specific conversation with anybody within Eli Lilly, and I say this with the exclusion of any conversations you may have had with an attorney, but do you recall ever having any conversations with anybody in Eli Lilly about the discontinuation warning in the Cymbalta label for the US?

A. The only conversation I ever remember was when we received notification of that -- that lawsuit.

402 403 Q. Okay. And following hearing about that lawsuit, did you discuss the lawsuit with any non-attorney individuals within Eli Lilly?

A. I'm not sure. I mean, I remember we -- there was a group of people that met and what I recall of that meeting was that we were made aware of this lawsuit and that we may be asked to produce documentation and they were just trying to get, "they," being Lilly legal, some background.

402 403 Q. Did you ever speak to Dr. Perahia about discontinuation symptoms?

A. No. Not that I recall.

402 403 Q. Okay. And do you recall anybody in Medical or in Regulatory ever saying to you, wow, I think that this label is misleading?

A. No.

Q. And obviously I don't mean that in quotes. I mean, something to that effect, do you ever recall having a conversation like that with anybody within Eli Lilly?

A. I do not recall, and I think I would

recall if something like that were brought to my attention.

Q. In 2012, were you ever made aware of something called the QuarterWatch Report related to Cymbalta?

A. It sounds familiar but I'm not sure. I don't -- nothing specific for Cymbalta.

Q. Okay. I might show it to you later. I just want to know do you have any independent recollection of something called a QuarterWatch Report that relates to Cymbalta? Do you have any recollection of that?

A. I don't.

MIL
402
403

Q. Okay. Are you familiar with the Institute for Safe Medication Practices?

A. I am.

Q. What is that organization?

A. It's a -- It's an independent business that really is interested in promoting safe use of -- well, safety medical practices including use of medications, so they were primarily about medication errors as I at least am familiar with that organization but maybe more broadly in terms of just safe use.

Q. And did you frequently read

publications by that organization?
A. No. Not -- not that I recall.
Q. Do you currently do that?
A. No.
Q. Okay. Is the Institution for Safe Medication Practices a respected organization?
MR. TEEL: Objection to lack of foundation.
THE WITNESS: My understanding is it is, yes. I mean, I have certainly heard of them in the -- yes.
BY MR. WISNER:
Q. Let me rephrase the question maybe.
Based on your experiences within Eli Lilly, was the Institute for Safe Medication Practices considered a reputable organization?
MR. TEEL: Objection. Lack of foundation.
THE WITNESS: Yes.
BY MR. WISNER:
Q. Do you recall ever speaking to somebody about the Institute for Safe Medicine Practices?
A. Now, we may have used ISMP for a medication error project that I worked on or maybe sort of wrapped up when I was working on

MIL
Lack of foundation.

Zyprexa with regard to mistaking the bottle of Zyprexa for a bottle of Zyrtec on the pharmacy shelves and the naming similarities. We worked with ISMP to differentiate the labels in a way that would help prevent that.

MIL 402

Q. So based on your time at Lilly, it's your understanding that Lilly would actually work with ISMP on occasion?

A. I am not a hundred percent certain ISMP was that company, but I think so.

Q. Okay.

A. So my recollection is yes.

Q. Do you recall ever having -- Do you know who Madeline Warick might be?

A. Yes.

Q. Who is she?

A. She is a medical -- medical -- I don't know if she is a Medical Director or if she was in medical.

Q. Did you have any occasion to interact with her while she was working at Eli Lilly with regards to Cymbalta?

A. I did.

Q. Okay. What was your inter -- what was the nature of your working relationship with

her?

A. So she was -- I think she was in a role very similar to Dr. Perahia in that she would provide -- she is a physician by training, and she would provide medical input, oversight into clinical development activities.

Q. And this is a very specific question but do you ever recall having a conversation with her about ISMP?

A. I don't, no.

MR. WISNER: Let's take a short break.

MR. TEEL: Sure.

THE VIDEOGRAPHER: Going off the record at 2:49 p.m.

(Whereupon, a short recess was taken.)

THE VIDEOGRAPHER: We are back on the record at 2:58 p.m.

BY MR. WISNER:

Q. Doctor -- I'm sorry, doctor. Are you a doctor?

A. Yeah. I mean, no one -- I never refer to myself as a doctor, but yes.

Q. But you are not a medical doctor; is that right?

A. No.
Q. Okay. I might call you doctor. That's just an instinctual thing but I apologize if -- Anyway, so let's get started.
Are you familiar with something that's called a Core Data Sheet?
A. Yes.
Q. What is the Core Data Sheet for a product?
A. So Core Data Sheet is a document that -- an internal document that would be developed to define core safety information for a product; and the intent by the Core Data Sheet, again, is sort of in the interest of harmonization of information across labeling globally.
Q. Would it be fair to say that labels are generally derived from the information contained on the Core Data Sheet?
A. Yes.
Q. And who creates the Core Data Sheet?
A. Well, I think it was -- At Lilly, I believe that development was owned by the Safety Group at Lilly, but I am not sure about this, but there would have been significant need for

* * *

BY MR. WISNER:

Q. Okay. It is true that Cymbalta is approved for other indications in Europe that it is not approved for in US, right?

A. I'm not sure actually.

Q. Have you ever heard of stress urinary incontinence?

A. Oh, yes. That's right. Yes. Yes. Uh-huh.

Q. Are you familiar with that Cymbalta is indicated for that treatment of that condition in different countries other than the US?

A. Yes. I am now that you say that, yes.

Q. Okay. Do you recall doing any work with regards to the SUI indication in the US?

A. No.

Q. Okay. The next sentence says, "Following abrupt or tapered discontinuation in placebo-controlled trials, the following symptoms occurred at 1 percent or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo," and it lists several symptoms there or side effects. Do you see that?

A. I do.
Q. Okay. What is your understanding of that sentence?
A. What the sentence is conveying that -- Okay. So, first of all, the systematic evaluation was from placebo-controlled clinical trials so that's the data source. The following symptoms occurred at an incidence of 1 percent or more and was higher in the Cymbalta-treated patients relative to placebo patients and it lists these terms.
Q. Now, these terms, these are MedDRA terms, correct?
A. I think they are MedDRA terms. They would be.
Q. Okay. So these are defined by that convention that we discussed previously?
A. Yes.
Q. And it says significantly higher rate. Is it your understanding that that's referenced to statistical significance?
MR. TEEL: Objection. Lack of foundation.
THE WITNESS: I don't know in this case; but in common practice, that use of the

402
403
Lack of foundation

word significantly higher would connote some sort of statistical inference.

BY MR. WISNER:

Q. Well, because significantly has multiple meanings, right?

A. Uh-huh.

Q. In statistics that means that the numbers observed in one arm versus another arm, the difference observed is not a product of chance?

MR. TEEL: Object to the form.

THE WITNESS: I don't think I would phrase it that way.

BY MR. WISNER:

Q. Please tell me what is your understanding of statistical significance.

A. That there is a -- How do I phrase this? That the observation is unlikely to be, maybe this is what you just said, the result of chance. Is that what you said?

Q. That's what I was saying inartfully.

A. That there is likely to be the result of other factors basically.

Q. And it also significantly has a layman meaning as well, right?

402
403
Lack of foundation.

MR. TEEL: Object to the form.
THE WITNESS: Yes.
BY MR. WISNER:
Q. Do you know which one this is referring to in this part of the label?
MR. TEEL: Object to the form.
THE WITNESS: Well, I don't know but, again, typical practice would be that the appearance of the word significant or significantly within the USPI is referring to a statistical finding.
BY MR. WISNER:
Q. And that inference is supported by the fact that it's referring to placebo-controlled trials related to Cymbalta?
A. That makes sense to me, yes.
Q. Okay. And then it would be an essentially higher rate in the duloxetine arm of those trials versus the placebo arm of those trials?
A. That's what this is saying.
Q. Okay. It says the following symptoms occur at 1 percent or greater. Do you understand what that phrase is referring to?
A. Yeah. It just -- It's setting a

threshold essentially for the analysis that based on the data that has been analyzed in this case, in my view, it would appear this is a very conservative approach and that you would be very inclusive in the types of terms that would qualify to be represented as an output of this kind of analysis.

Q. Okay. And the -- So it would be fair to infer then from this warning that there is a 1 percent or greater chance that upon discontinuation, abrupt or tapered for Cymbalta, a person would experience dizziness?

A. No. That's not the way this -- That's not the way I would understand this. I would say this is saying that for patients who discontinued duloxetine relative to those who discontinued placebo in trials, there was a higher incidence of these events relative to the placebo arm.

Q. Now, it doesn't say specifically what the percentage for those incident rates were for those specific side effects, correct?

A. It's only saying that they occurred at least 1 percent or more of the time.

Q. So it's possible -- and that's

referring to these specific MedDRA terms, right?

A. Right.

Q. So for dizziness it's 1 percent or greater?

A. It's saying for -- yeah, for dizziness, it occurred at least at 1 percent and at a higher rate than the placebo arm.

402
403
Lack of foundation.

Q. Now, 1 percent or greater, that means it's possible that dizziness occurred in a hundred percent of patients, right?

A. It's possible. It's greater than 1 percent.

Q. And it's also possible that it occurred in 1.1 percent, right?

A. That's right.

Q. So based on the information contained in this label, the possible range of dizziness with regards to the 1 percent is somewhere between 1 and a hundred percent?

A. Right.

Q. And nowhere in that paragraph does it specifically state what the percentage is for each one of those MedDRA terms?

A. No. It's not -- This paragraph is listing the, for lack of a better way of

phrasing it, constellation of potential events that could -- that were observed following discontinuation.

Q. And also in that paragraph, it doesn't say what the likelihood that a patient would experience at least one of those symptoms, correct?

A. No. That's not what this is conveying.

Q. Okay. So there is no overall incident rates of just general discontinuation symptoms in that paragraph?

MR. TEEL: Object to the form.

THE WITNESS: No. That's not what this -- again, this is conveying here are the kind of events that were observed, so for healthcare professionals to understand, here are the types of symptoms associated with discontinuation events with Cymbalta.

BY MR. WISNER:

Q. The next paragraph reads, "During the marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the

following:" And it lists again a bunch of terms. Do you see that?

A. I do.

Lack of foundation.

Q. Now, I want to break that down a little bit here. It says during the marketing of other SSRIs and SNRIs, what is that referring to?

MR. TEEL: Objection. Lack of foundation. You can answer.

THE WITNESS: Yes. I'm not sure I guess, but my educated guess is that this is referring to sort of a class kind of labeling change.

BY MR. WISNER:

Q. And it says there have been "spontaneous reports of adverse events." Is the phrase "spontaneous reports of adverse events," is that a term of art?

A. It is.

Q. What is that?

A. That's referring to postmarketing Adverse Event Reports. Those are commonly referred to as Spontaneous Reports.

Q. And can you explain to the jury what spontaneous means in that context because I think -- Could you please explain to the jury

what that means?

A. Yes. Spontaneous is a term that is used to indicate that the terms were not solicited. For example, like in a clinical trial setting, the clinical trial investigators ask have you had any adverse events, what were those, et cetera, so you are actually soliciting that information; whereas, in the postmarketing setting, these would be terms, events, cases that would be reported to Lilly unprompted without any sort of solicitation through the call center or maybe through a sales rep or other mechanism.

Q. Okay. Is it your under -- Okay. Now just take a second and just finish reading through the rest of the section just so you have a sense of what's in it.

A. Okay.

Q. Let me know when you are done.

A. Okay. I am finished.

Q. Keep that Exhibit 1 open to that section because we are going to be referencing it.

A. Okay.

* * *

Committee, that's the Advisory Committee that we were just discussing?

A. That is.

Q. Okay. And the Lilly Briefing Doc, that's the document that Lilly submitted to the FDA in anticipation of that meeting?

A. Correct.

Q. Can you just turn to page -- it's a fairly lengthy document here.

A. Uh-huh.

Q. It runs from CYM-01939316 through CYM-01939474. Is this the Briefing Document?

A. That's what it appears to be, yes.

Q. It's about 159 pages; is that right?

A. That's -- yep. Yes.

Q. And that's consistent with what you remember the briefing document being that was submitted to the FDA?

A. I actually thought it was shorter, but, yes. This sounds right.

Q. Okay. And it says down here it says, "Available for public disclosure without redaction," right?

A. Right.

Q. And that was what you were mentioning

before, that this was actually posted and made available online?

A. Right.

(Whereupon, Deposition Exhibit No. 13 was marked and dated.)

BY MR. WISNER:

402 403

Q. Okay. Doctor, I have handed you what I have marked as Exhibit 13, right?

A. Right.

Q. Okay. This is an E-mail exchange. If you look down towards the bottom, there is an E-mail from you to Bryan E. Boggs. Do you see that?

A. I do.

Q. And you said, "FYI, in case you haven't seen this. Includes dulox safety reviews." Do you see that?

A. I do.

Q. Okay. And this is a document that's Bates stamped CYM-02053002. Now, Doctor -- Mr. Kuntz, this -- do you know what you were referring to in this E-mail?

A. I don't recall. I'd have to look here. Okay. I actually still don't even know after looking at it what this is exactly referring to.

Okay.

Q. Well, above it Bryan Boggs says, "Please convene a group to discuss this posting to the FDA website." Do you see that?

A. I do.

Q. And, "There are three documents I have attached. I believe we have seen the first memo regarding medication errors already. All of these are dated 2007 and I don't believe pose any issues we have not already addressed. Label changes suggested within the bleeding report appear to have been made already. Carole, would you look at this to determine when these changes were actually implemented."

Did I read that right?

A. Yes.

Q. Okay. So it appears that you had sent a link to several documents that had been posted on the FDA website; is that fair?

A. Uh-huh.

(Whereupon, Deposition Exhibit No. 14 was marked and dated.)

BY MR. WISNER:

Q. Okay. I am handing you what I have marked as Exhibit 14 to your deposition. This

is one of the attachments that Bryan had to his E-mail. Do you recognize this document, Doctor? Do you recognize this document?

A. I don't.

Q. What does it appear to be?

A. Well, it's some sort of memo from -- from within FDA. Medication Error Report.

Q. So it's a memorandum that was prepared within the FDA?

A. Within the FDA, right.

Q. Okay. Do you know if this memorandum was ever shared with Eli Lilly?

A. Well, it was -- what I think it sure looks like happened is this memo was posted. This was the document that was posted to FDA's website and I was on a -- basically a list serve or something where FDA, you know, sends out updates and that's how I found this document.

Q. But do you know whether in 2007 this document was given to Lilly?

A. Oh, I beg your pardon. I didn't understand your -- the timing. No. I don't know.

Q. And just to clarify, the E-mail that you are mentioning that you sent, that was in

2009, right?

A. That's right.

Q. And this memo is dated 2007?

A. Right.

Q. Okay. Do you know whether or not in 2007 this memo was shared with Lilly?

A. I don't.

Q. Okay. All right. Well, this is -- and in the Executive Summary it says, "During routine postmarketing surveillance of medication errors, DMETS identified a signal involving the opening of Cymbalta capsules prior to administration to achieve a lower dose of the drug."

What is DMETS?

A. It's the FDA Division of Medication Errors and Technical Support.

Q. Okay. And it says identified a signal. What is your understanding of that word "signal"?

A. Yeah. That's a -- that's a term that would signify that in the review of aggregated safety data from the errors database, this issue came up somehow in their analysis. There is lots of probably different algorithms that they

would have applied but --

Q. And you have familiarity with such things as signals based on your work in the Pharmacovigilance Group, right?

A. Yeah. That's right.

Q. Okay. It says here that there has been a signal that opening of Cymbalta capsules prior to administration to achieve a lower dose of the drug.

Do you ever recall discussing this issue at Eli Lilly in your regulatory capacity?

A. I don't.

Q. Okay. If you turn the page, on Page 2, under Section 3, it says, "During routine monitoring of medication errors, DMETS received a case where a patient intentionally opened a Cymbalta capsule to achieve a lower dose."

During your time at Eli Lilly, do you recall ever having any discussions with anyone at Eli Lilly about people opening up the capsules to create smaller dosages for Cymbalta?

A. I don't.

Q. Do you recall whether or not anyone at Eli Lilly took actions to update the label or make changes to the US label in response to the

potential of patients opening up Cymbalta capsules?

A. I don't recall that.

Q. Okay. If you turn to Page 3, under Section C, Wrong Technique, go down midway through the paragraph. It says, "One (n=1) case involved opening 20 milligram capsules while tapering off Cymbalta to avoid withdrawal effects."

Do you see that?

A. I do.

Q. In this document, the FDA has identified a signal and supporting that identification of that signal is discussing at least one incident where a patient has opened the 20 milligram capsule so as to avoid withdrawal effects, correct?

A. That's what this report is stating.

Q. Do you know whether or not Lilly took any actions to update the label to warn patients not to open up the 20 milligram capsules to avoid withdrawal effects?

A. I don't recall.

Q. Do you know if Lilly, at any time, considered submitting a prior approval

supplement to obtain smaller doses of Cymbalta for the purposes of tapering?

A. No. I'm trying to recall if there was a lower dose for the pediatric studies but I just don't recall.

Q. Okay. So do you recall -- Well, do you recall whether or not Lilly ever did try to obtain a smaller than 20 milligram dose of Cymbalta -- Sorry. Let me rephrase that.

402
403

Do you recall whether or not -- Do you know whether or not Lilly ever tried to obtain approval for a dosage of Cymbalta less than 20 milligrams?

A. I don't know.

402
403
MIL

Q. Okay. Turn to Page 6, it says, Upon -- under Section 3, the paragraph under Section 3 -- Well, the section reads Institute of Safe Medicine Practices Outpatient Medication Errors. And then underneath that it says, "Upon DMETS request, the Institute for Safe Medication Practices (ISMP) searched their database for outpatient medication errors involving Cymbalta."

Do you -- The ISMP, that's the organization that published that QuarterWatch

report we mentioned earlier, right?

A. Right.

Q. And it appears here that the FDA's DMETS has requested data from that organization?

A. Yes. That's what it looks like.

Q. Okay. If you turn to Page 7 under Section A, Patients Attempting to Reduce or Avoid Adverse Effects of Cymbalta, do you see that section?

A. Yes.

Q. All right. Second to the last sentence in that paragraph, the first paragraph it reads, "Three cases (n=3) reported patients opening the capsules to create a dose of Cymbalta less than 20 milligrams in an attempt to reduce the adverse events associated with the discontinuation of Cymbalta."

Would it have been possible for Lilly to have submitted an SNDA -- or sorry -- a preapproved -- Would it have been possible for Lilly to have submitted a Prior Approval Supplement to obtain smaller doses -- approval -- to obtain approval of smaller doses of Cymbalta below 20 milligrams?

MR. TEEL: Objection. Calls for

speculation. Lack of foundation.

THE WITNESS: I mean, it's not as simple as just submitting that, you know, request to FDA. They would expect to have data to support the use of that and you would have to do quite a bit, I would think, of clinical evaluation of that lower dosage form.

BY MR. WISNER:

Q. Do you know if Lilly ever did conduct clinical trials to evaluate the discontinuation effects of a subtherapeutic dose below 20 milligrams?

A. I'm not aware.

Q. Okay. Based on your understanding of the CBE regulation, would Lilly have been able to make changes to the Cymbalta label advising patients that there was no way to taper below 20 milligrams?

MR. TEEL: Objection. Again, lack of foundation.

THE WITNESS: I'm not sure I quite understand what you are asking. Can you rephrase it?

BY MR. WISNER:

Q. Using the CBE regulation, would Lilly

have been able to make changes to the discontinuation warning in the Cymbalta label for the US advising patients that there was no way to taper below 20 milligrams?

A. Well, again, I think it could have been possible is the best way to answer that question.

Q. Thank you. You can't say for sure right now that it would have been impossible?

A. Yeah. That's right.

Q. Okay. Do you recall ever being consulted about potential changes to the Japanese label for Cymbalta?

A. I believe this was something we may have discussed in preparation for today. I am not a hundred percent sure.

Q. Okay. Well, independent of what any lawyer may have said to you --

A. Right.

Q. -- do you recall that your approach to make changes -- your approach about the Japanese label?

A. I honestly, at the moment, I don't remember that. For some reason, though, there is something in that -- anyways, I'm sorry. I

* * *

CERTIFICATE

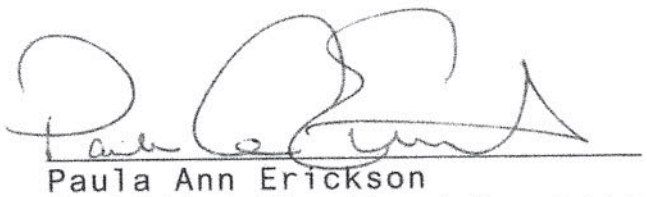
I, Paula Ann Erickson, Certified Professional Reporter, Registered Professional Reporter and Notary Public, do hereby certify:

That the witness in the foregoing deposition named was present at the time and place therein specified;

That the said proceeding was taken before me as a Notary Public at the same time and place and was taken down in shorthand writing by me;

That this transcript is a true and accurate transcript of my shorthand notes so taken, to the best of my ability.

I further certify that I am neither counsel for nor related to or employed by any of the parties to this action and that I am not a relative or employee of any counsel employed by the parties hereto or financially interested in the action.



Paula Ann Erickson
Certified Shorthand Reporter
Registered Professional Reporter
License No. 084-003899
Notary Public

Dated this 15th day

of May, 2015.

Ali v. Eli Lilly and Company
Hagan-Brown v. Eli Lilly and Company
Lilly's Objections to Plaintiffs' Deposition Designations
Matthew Kuntz

Lines	Objection(s)	Explanation
30:25-31:5	402	Mr. Kuntz's lack of recollection as to whether Lilly submitted a Changes Being Effected (CBE) label change is irrelevant. Moreover, Lilly's CBEs related to products other than Cymbalta are irrelevant.
31:6-31:14	402	Mr. Kuntz's recollection that Lilly submitted Prior Approval Supplements to FDA and that he "wouldn't be surprised" if CBEs were submitted to FDA is irrelevant. The question is not tied to Cymbalta in any way.
31:15-31:25	402 Lack of foundation.	Mr. Kuntz's testimony that CBEs and Prior Approval Supplements were normal in Lilly's course of business is irrelevant. Counsel's question whether such submissions are common in Lilly's interactions with FDA lacks foundation to establish that Mr. Kuntz can speak to the course of Lilly's interactions with FDA.
56:4-11	403 Lack of foundation.	Testimony about Mr. Kuntz's recollection whether Lilly had any "regulatory activities" concerning discontinuation is unduly prejudicial. Plaintiffs are improperly and falsely suggesting that discontinuation symptoms were not important to Lilly and that Lilly did not take any actions related to discontinuation symptoms. Additionally, counsel's question about whether Mr. Kuntz recalls regulatory interactions related to discontinuation symptoms lacks foundation to establish that Mr. Kuntz can testify to the breadth of Lilly's interactions with FDA concerning Cymbalta.
65:5-65:15	402 403	Mr. Kuntz's on-the-spot recollection of discontinuation symptoms is irrelevant and prejudicial where discontinuation symptoms are listed in great detail in Cymbalta's label, clinical trials, and various other scientific and regulatory documents. Counsel's "memory test" is designed to mislead the jury to believe that Lilly did not adequately research or understand the symptoms.
65:16-66:1	402	This designation will be subject to Lilly's

Lines	Objection(s)	Explanation
	403 MIL	European Labeling MIL. Additionally, Mr. Kuntz's on-the-spot recollection of the frequency of discontinuation symptoms is irrelevant and prejudicial where their frequency is listed in great detail in Cymbalta's label, clinical trials, and various other scientific and regulatory documents.
66:2-66:8	402 403	Mr. Kuntz's testimony concerning whether he considered discontinuation symptoms "important" is irrelevant and prejudicial. Lilly's and its employees' views about the relative importance of specific side effects is irrelevant, and risks undue prejudice in suggesting that Lilly prioritized certain side effects or safety issues over others.
66:13-66:17	402 403	Mr. Kuntz's lack of recollection of any discussion within Lilly about possible deficiencies in the Cymbalta label concerning discontinuation is irrelevant and prejudicial. Plaintiffs are attempting to suggest that internal Lilly discussions about the label were not important enough to the company to be remembered.
66:18-67:3	402 403	Mr. Kuntz's recollection that the only conversation he could recall concerning discontinuation symptoms was related to litigation is irrelevant and prejudicial. Mr. Kuntz's recollection about litigation was undoubtedly jogged by his involvement in this litigation and the recency of such communications, whereas his natural lack of recollection about older communications should not be allowed to prejudice Lilly by suggesting that Lilly's only concern was with legal liability rather than patient safety.
67:4-67:13	402 403	Mr. Kuntz's recollection that the only conversation he could recall concerning discontinuation symptoms was related to litigation is irrelevant and prejudicial. Mr. Kuntz's recollection about litigation was undoubtedly jogged by his involvement in this litigation and the recency of such communications, whereas his natural lack of recollection about older communications should not be allowed to prejudice Lilly by suggesting that Lilly's only concern was with legal liability rather than patient safety.

Lines	Objection(s)	Explanation
67:14-67:16	402 403	Mr. Kuntz's lack of recollection of any discussion with Dr. Perahia about discontinuation symptoms is irrelevant and prejudicial. Plaintiffs are attempting to suggest that internal Lilly discussions about the label were not important enough to the company to be remembered.
67:17-68:2	402 403	Mr. Kuntz's lack of recollection of any discussion within Lilly about possible deficiencies in the Cymbalta label is irrelevant and prejudicial. Plaintiffs are attempting to suggest that internal Lilly discussions about the label were not important enough to the company to be remembered.
68:14-24	MIL 402 403	This designation will be subject to Lilly's MIL about the QuarterWatch publication. Moreover, Mr. Kuntz's independent knowledge of and familiarity with the organization that publishes QuarterWatch is irrelevant as well as unduly prejudicial in that Mr. Kuntz's familiarity is based on the organization's work related to confusion about drug names (*see* Kuntz Dep. at 69:23-70:5) rather than their publications about labeling adequacy.
69:14-19	MIL Lack of foundation.	This designation will be subject to Lilly's MIL about the QuarterWatch publication. Moreover, counsel's question lacks foundation as to Mr. Kuntz's understanding about other Lilly employees' views about the Institute for Safe Medication Practices.
70:6-71:9	MIL 402	This designation will be subject to Lilly's MIL about the QuarterWatch publication. Moreover, Mr. Kuntz's lack of recollection as to whether Institute for Safe Medication Practices was the organization he recalled or whether he ever discussed it with Dr. Wohlreich is irrelevant
93:19-94:2	402 403 Lack of foundation.	Counsel's question about whether the Cymbalta label refers to the concept of statistical significance lacks the necessary foundation of Mr. Kuntz's knowledge of statistical significance. Moreover, Mr. Kuntz's understanding of whether the label refers to statistical significance is irrelevant and prejudicial in suggesting that the language in the label connotes only a statistical

Lines	Objection(s)	Explanation
		meaning.
94:7-94:13	402 403 Lack of foundation.	Counsel's question about the concept of statistical significance lacks the necessary foundation of Mr. Kuntz's knowledge of statistical significance. Moreover, Mr. Kuntz's understanding of whether the label refers to statistical significance is irrelevant and prejudicial in suggesting that the language in the label connotes only a statistical meaning.
97:8-97:20	402 403 Lack of foundation.	Lilly has not generally objected to questions asking Mr. Kuntz for his understanding of the contents of Cymbalta's label to the extent that they reflect the underlying text of the label and/or the underlying data. However, questions about whether the "1% or greater" language could include effects that occurred at a rate of 100% lack foundation. No discontinuation symptom in any study occurred at a rate even approaching 100%. (The most common single symptom in the 2005 Perahia study occurred at a rate of 12.4%.) Plaintiffs' designation therefore falsely suggests that some symptoms may have occurred at a rate approaching 100% and is therefore irrelevant, prejudicial, misleading, and likely to cause confusion.
99:4-99:12	Lack of foundation.	Counsel's question about the "marketing of other SSRIs and SNRIs" lacks foundation to establish that Mr. Kuntz has an understanding of the marketing of other SSRIs and SNRIs.
196:7-202:5	402 403	Mr. Kuntz's testimony that he does not recall an email exchange regarding patients breaking open capsules is irrelevant, and risks prejudice to Lilly by implying that Lilly did not take FDA reports about patient issues seriously enough to allow Lilly employees to later recall them. In addition, evidence regarding the opening of capsules is irrelevant and prejudicial in this case where neither Plaintiff alleges that she broke open capsules and neither prescriber instructed Plaintiff to break open capsules. Moreover, Plaintiffs voluntarily withdrew their design defect claims.
202:10-202:14	402 403	Evidence regarding doses below 20mg are irrelevant and prejudicial in this case where neither Plaintiff took 20mg at any point and where neither prescriber testified that he or she

Lines	Objection(s)	Explanation
		sought a dosage below 20mg. Moreover, Plaintiffs voluntarily withdrew their design defect claims.
202:15-204:7	402 403 MIL	This designation will be subject to Lilly's MIL about QuarterWatch. In addition, evidence regarding an FDA document regarding the opening of capsules is irrelevant and prejudicial in this case where neither Plaintiff alleges that she broke open capsules and neither prescriber instructed Plaintiff to break open capsules. Moreover, Plaintiffs voluntarily withdrew their design defect claims.